

USSN 10/016,821  
Response to Office Action dated June 7, 2005  
Art. Docket 3267/FLK (032878-00052)

## **II. REMARKS**

Applicants have carefully reviewed the Examiner's Office Action dated June 7, 2005, rejecting claims 1 to 4 under 35 U.S.C. 112(a) and 112(b), and under 35 U.S.C. 103(a) as being unpatentable over WO 00/78292 in view of Serpelloni et al. (USP 5,573,777).

Applicants traverse these rejections. In view of the above amendments made to the claims and for the reasons provided below, early allowance of the pending claims is respectfully requested.

### **I. Rejections under 35 U.S.C. 112(a)**

In the office action, the Examiner pointed out that the claims are too broad as to the scope of pharmaceutically acceptable excipients and an ordinary skilled person in the art would be required to do undue experimentation in order to determine what excipients will result in a tablet which disintegrates within 60 seconds.

In this regard, first of all, the Examiner's kind attention is invited to the fact that claims 1 and 4 have been now amended to clearly express the required amounts of the components (ii) and (iii), i.e., spray-dried mannitol and crospovidone as being sufficient to cause disintegration of the tablet within 60 seconds; and to clearly define the kinds and amount of the component (iv), i.e., one or more pharmaceutically acceptable excipients as being selected from an organic acid, effervescent agent, sweetening agent, lubricant, diluent and flavor, and as not preventing the tablet from disintegrating in the oral cavity within 60 seconds, respectively, by way of the above amendment.

The tablet of the present invention is characterized in that it comprises spray-dried mannitol and crospovidone as essential functional components. Other ingredients such as pharmaceutically acceptable excipients (component (iv)) required in formulating a tablet may be suitably selected from those well known in the art as long as they do not prevent the tablet from disintegrating in the oral

USSN 10/016,821  
Response to Office Action dated June 7, 2005  
Atty. Docket 3267/FLK (032878-00052)

cavity within 60 minutes. No undue experimentation is needed to find excipients satisfying this condition as will be shown below.

To establish that no undue experimentation is needed to find excipients which disintegrate the inventive tablet within 60 minutes, the applicants have conducted a series of experiments, revealing many excipients other than those disclosed in the Examples of the present specification as originally filed, which disintegrates the inventive tablet within 60 seconds. The results of the experiments are enclosed herewith as a Declaration.

As can be seen from the Declaration, it is extremely easy to determine whether or not certain excipient makes the inventive tablet disintegrate within 60 minutes and such determination is well within the ability of one skilled in the art.

Therefore, it is respectfully submitted that claims 1 and 4, as amended, clearly define the scope of "excipients."

## II. Rejections under 35 U.S.C. 112(b)

It is believed that the above rejection has been overcome because the constitutional elements pointed out by the Examiner have been clearly recited in claims 1 and 4 by way of the above amendment.

## III. Rejection of Claims 1 to 4 under 35 U.S.C. 103(a) over WO 00/78292 in view of Serpelloni et al. (USP 5,573,777).

At first, with regard to the cited references by the Examiner, the Examiner's kind attention is invited to the fact that WO 00/78292 cited as a primary reference was published on December 28, 2000, which is later than the priority date of the present application, i.e., March 25, 1999 (please be informed that the present application is a CIP application of USSN 09/536,163 filed on March 25, 2000 claiming a

USSN 10/016,821  
Response to Office Action dated June 7, 2005  
Art. Docket 3267/FLK (032878-00052)

priority of Korean Patent Application No. 1999-10172 filed on March 25, 1999). Acknowledgement of the claim of priority and receipt of the priority documents appears in the office action of June 14, 2005.

Accordingly, WO 00/78292 cannot be considered as a prior art reference against the present application, and the Serpelloni et al. patent cited by the Examiner as a secondary reference does not single-handedly render the present invention in claims 1 to 4 obvious.

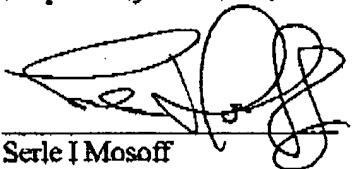
Therefore, it is submitted that the present invention is not obvious over the combination of the cited references.

### III. Conclusion

In view of the foregoing amendments and discussions, it is respectfully submitted that the present invention as defined in the pending claims 1 to 4 is in full compliance with all the statutory requirements, and therefore, it is earnestly requested that the Examiner's rejections be withdrawn and the pending claims be allowed in their present form.

Any fee due with this paper, not fully covered by an enclosed check, may be charged on Deposit Account 50-1290.

Respectfully submitted,



Sarel I. Mosoff  
Reg. No. 25,900

**CUSTOMER NUMBER 026304**

USSN 10/016,821  
Response to Office Action dated June 7, 2005  
Atty. Docker 3267/FLK (032878-00052)

KATTEN MUCHIN ROSENMAN LLP  
575 Madison Avenue  
New York, New York 10022-2585  
Tel: (212) 940-8717  
Fax: (212) 940-8987